

Wednesday, March 12 2020

Utah Public Health Laboratory

Interim Guidelines for Clinical Specimens from Patients Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19)

The CDC's diagnostic test has been authorized by FDA under the Emergency Use Authorization (EUA). Utah Public Health Laboratory is performing the EUA assay. Samples are received at UPHL, M-F 0800-1700 and Saturday 0800-1600. Standard Precautions should be taken in collecting and handling specimens that may contain SARS COV2 virus. Timely communication between clinical, laboratory, and UDOH/Local Health Department staff is essential to minimize the risk incurred in handling specimens from patients with possible COVID-19 infection. General and specific biosafety and submission guidelines for handling, processing, and shipping COVID-19 specimens are provided.

General Guidelines for COVID-19

For initial diagnostic testing for SARS COV2 virus, CDC recommends collecting and testing a **single upper respiratory specimen (NP – nasopharyngeal swab) collected and received in appropriate transport media**. Upper respiratory samples (nasopharyngeal AND oropharyngeal swabs), and lower respiratory samples (sputum, if possible) for those patients with productive coughs are acceptable specimen types, but not required. Induction of sputum is not indicated.

Store specimens at 2-8°C and ship to Utah Public Health Laboratory (UPHL) on ice packs. Label each specimen container with at least two unique identifiers. Frozen specimens should be shipped on dry ice with appropriate shipping protocols. Questions regarding laboratory response, specimen submission, or testing guidance can be directed to the UPHL Biothreat response team at 801-560-6586 (24/7).

Respiratory Specimens

A. Lower respiratory tract

1. Broncho alveolar lavage (BAL), tracheal aspirate



Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container. Refrigerate specimen at 2-8°C and ship to UPHL on ice pack.

2. Sputum

Refrigerate specimen (sterile, leak-proof, screw-cap sputum collection cup or sterile dry container) at 2-8°C and ship to UPHL on ice pack.

B. Upper respiratory tract: Nasopharyngeal swab AND oropharyngeal swab (NP/OP swab)

Use only synthetic fiber swabs with plastic shafts in sterile tubes containing 2-3 ml of **viral transport media**. NP and OP specimens can be kept in separate vials, or submitted in a single transport tube. Refrigerate specimen(s) at 2-8°C and ship to UPHL on ice pack.

C. Nasopharyngeal wash/aspirate or nasal aspirate

Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container. Refrigerate specimen at 2-8°C and ship to UPHL on ice pack.

Testing for other respiratory pathogens should be done as part of the initial evaluation by the provider. If a PUI tests positive for another respiratory pathogen, after clinical evaluation and consultation with public health authorities, they may no longer be considered a PUI.

STORAGE

Store specimens at 2-8°C for up to 72 hours after collection. If a delay in testing or shipping is expected, store specimens at -70°C or below.

NOTES ON COLLECTION

- Swabs are sent in **Viral Transport Media** (or, **Universal Transport Media**, UTM), NOT bacterial media.
- Send the swabs individually, as a pair, or combined in the same transport tube.
- Use only synthetic fiber swabs with plastic shafts. No metal, no wood.
- Storage: 4-8 C, -70 if >72hr.
- Package as Category B (like most send-outs).
- Ship on wet ice/cold pack.



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Packing, Shipping and Transport

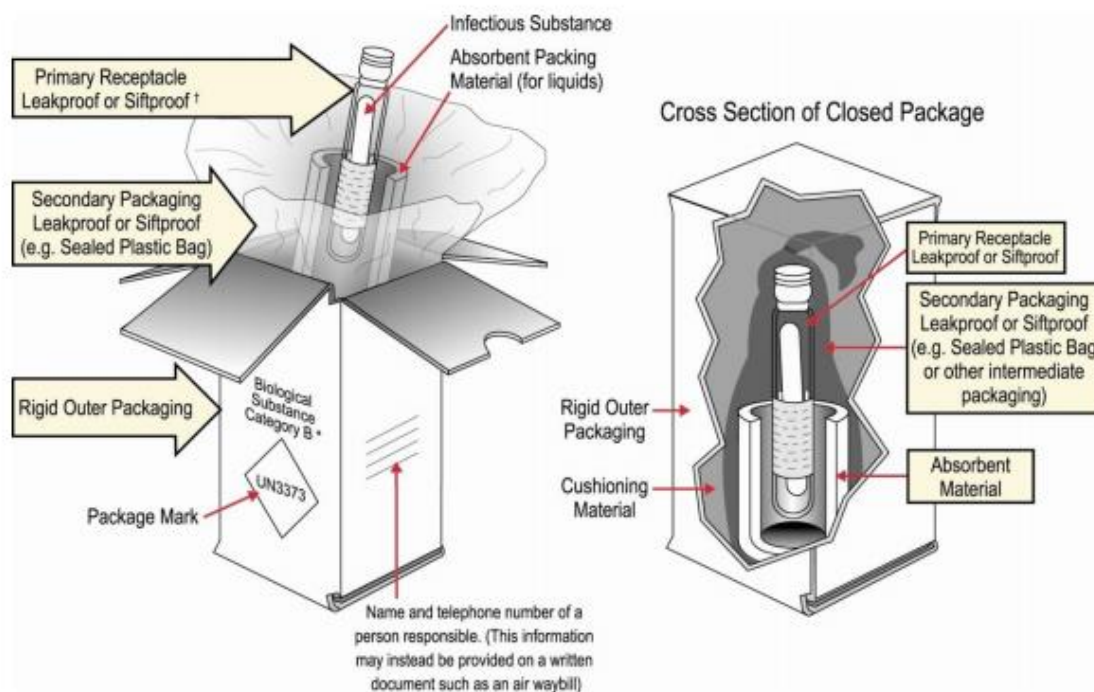
Specimens transported by motor vehicle fall under DOT regulations, which allows packaging exceptions for some Biological substances, category B. Many hospital labs offer specimen courier service for other infectious tests. Specimens in biohazard bags, which those couriers then place in closed containers in their vehicle for transport to a reference lab for testing are acceptable for UPHL.

If you follow DOT regulations, patient specimens (not category A) are not regulated as infectious substances when transported by an "exclusive use courier." This means the shipper decides how to package it by following OSHA regulations, in-house protocols, and safe practices considering both the safety of the courier and personnel in the receiving lab, and protocols that ensure specimen integrity when using an exclusive courier.

Packaging, shipping, and transport of specimens from suspect cases or COVID-19 PUI's must follow the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulations for shipment by air transport. Follow shipping regulations for UN 3373 Biological Substance, Category B when sending potential COVID-19 specimens by transport other than "exclusive use courier".



UN 3373 Category B schematic for packaging



General Biosafety Guidelines (for working with potentially infectious materials)

Clinical laboratories performing routine hematology, urinalysis, and clinical chemistry studies, and microbiology laboratories performing diagnostic tests on serum, blood, or urine specimens should follow standard laboratory practices, including Standard Precautions, when handling potential 2019-nCoV specimens. Appropriate physical containment devices (e.g., centrifuge safety buckets; sealed rotors) should be used for centrifugation. Ideally, rotors and buckets should be loaded and unloaded in a BSC.

Testing of PUI specimens that involve any procedure with the potential to generate fine-particulate aerosols or droplets (e.g., vortexing) should be performed in a Class II Biological Safety Cabinet (BSC). In the case of lack of access to a BSC, or any procedures outside of a BSC eye and face protection (e.g. goggles, mask, and face shield) or other physical barriers (e.g. splash shield) should be used to minimize the risk of exposure to laboratory staff.

After specimens are processed, decontaminate work surfaces and equipment with appropriate disinfectants. Use EPA-registered hospital disinfectants with label claims to be effective against other respiratory pathogens, such as seasonal influenza and other human coronaviruses. Follow manufacturer's recommendations for use – dilution (i.e., concentration), contact time, and care in handling.

For COVID-19 laboratory waste, follow standard procedures associated with other respiratory pathogens, such as seasonal influenza and other human coronaviruses.

Specific Biosafety Guidelines

The following activities may be performed in BSL-2 facilities using standard BSL-2 work practices:

- Routine examination of bacterial and mycotic cultures
- Routine staining and microscopic analysis of **fixed** smears
- Final packaging of specimens for transport to diagnostic laboratories for additional testing. Specimens should already be in a sealed, **decontaminated primary container**.
- Inactivated specimens (e.g., specimens in nucleic acid extraction buffer)
- Pathologic examination and processing of formalin-fixed or otherwise inactivated tissues
- Molecular analysis of extracted nucleic acid preparations
- Electron microscopic studies with glutaraldehyde-fixed grids



The following activities involving manipulation of potentially infected specimens should be performed in a Class II BSC:

- **Aliquoting and/or diluting specimens**
- **Inoculating bacterial or mycological culture media**
- Performing diagnostic tests that do not involve propagation of viral agents in vitro or in vivo
- Nucleic acid **extraction procedures** involving potentially infected specimens
- **Preparation and chemical- or heat-fixing of smears for microscopic analysis**

For additional detailed instructions please refer to the following:

Biosafety in Microbiological and Biomedical Laboratories (BMBL) – Fifth Edition

Laboratory Biosafety Manual – Third Edition

<https://www.cdc.gov/coronavirus/2019-nCoV/index.html>

<https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>

<https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html>

